

**RULE 132 AFFIDAVIT**

**In the United States Patent and Trademark Office**

Applicant: Dr. William J. Kokolus, et. al.

Serial No.: 09/552,461

Filed: April 18,2000

Examiner: Mary K. Zeman

Art Unit: 1631

For: IMPROVED METHOD OF IDENTIFYING AND LOCATING

IMMUNOBIOLOGICALLY ACTIVE LINEAR PEPTIDES

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MAR 22 2002

TECH CENTER 1600/2900

**DECLARATION UNDER 37 C.F.R. Section 1.132**

I, Dr. William Joseph Kokolus, declare and say:

That I am a citizen of the United States of America currently residing at 69 Ferndale Avenue, Kenmore, NY 14217 USA;

That I am the sole inventor in the above-identified patent application;

That I was graduated in 1969 from the State University of New York at Buffalo, Buffalo, New York with a Bachelor of Arts degree in Mathematics and in 1971 from Michigan State University, East Lansing, Michigan with a Master of Science degree in Microbiology and Public Health. I also was graduated in 1992 from The University of Texas Health Science Center, M.D. Anderson Cancer Center, Houston, Texas with a Ph.D. in biomedical sciences with a concentration in immunology;

That since 1987 I have been conducting independent research in the field of immunology working at The University of Texas Science Health Center, M.D Anderson Cancer Center as a pre-doctoral, post doctoral scientist and research associate before establishing the predecessor to my present company in 1997;

That I have published two papers, one of which is an abstract, and also conference proceedings and have made approximately 5 presentations at professional meetings in the field of immunology;

That I am a co-inventor on three issued U.S. patents related to the instant field of immunology;

That I am familiar with the above-identified patent application and with the referenced patent Kokolus et al, US Patent 5,807,978.

Hereby, I declare that any invention disclosed but not claimed in the reference patent Kokolus et al was derived from me and is thus not the invention "by another".

That the undersigned declares further that all statements made herein of his own knowledge are true and that all statements made on information and belief are believed to be true; and further, that these statements were made with knowledge that willful false statements and the like do made are punishable by fine or imprisonment or both, under Section 1001 of Title 18 of the United States code and that such willful false statements may jeopardize the validity of the application or any patent issuing thereon;

Further declarant saith not.

Date: 3-13-2002

William J. Kokolus, Ph.D.  
Dr. William J. Kokolus

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meetings in the field of immunology;

That I am a co-inventor on three issued U.S. patents related to the instant field of  
immunology;

That I am familiar with the above-identified patent application and with the reference cited by the Examiner, the Dowell et al patent U.S. No. 5,599,677 issued Feb. 4, 1997 (the Dowell '677 patent);

That tests were commissioned by me to detect either the anti-free or the anti-total PSA immunologic activity present in rabbit antisera elicited by six respective Ho-Hi-Ho PSA peptides found in U.S. Patent No. 5,807,978 to Kokolus, et. al. The six claimed anti-Ho-Hi-Ho PSA peptide antisera and two control anti-PSA monoclonal antibodies were reacted with free PSA and complexed PSA-ACT, respectively;

That the above mentioned tests were conducted using standard ELISA technology and procedures;

That, as seen in the attached graph, rabbit antisera elicited by five of the Ho-Hi-Ho PSA peptides, respectively, detected either free or total PSA;

That the results demonstrate that in each of the five positive tests, only one anti-PSA peptide antisera lot was required to detect either free or total PSA whereas for the positive tests disclosed in Dowell '677 to detect free and total PSA the combined use of at least two distinct lots of antibodies were required;.

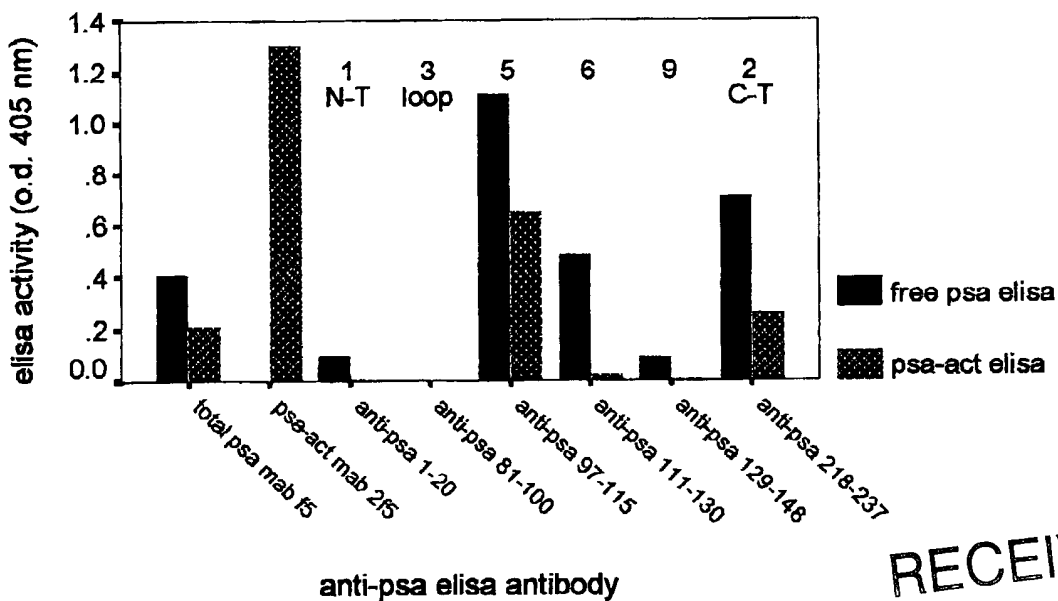
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Date: 3/13/2002

William J. Kokolus, Ph.D.  
Dr. William J. Kokolus

The Claimed Anti-PSA Peptide Antisera Can  
Detect Free PSA and Total PSA (Free PSA+PSA-ACT)



anti-psa elisa antibody

Claimed anti-psa peptide antisera (rabbit) dilutions: 1:1000; mab ascites  
dilutions: f5, 1:5000; 2f5, 1:10E9 (c) 2002 Fountain's Rainbow Vaccine

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